Réseau RRISIQ Network

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Quebec Network on Nursing Intervention Research

McMaster University

EMBEDDING A PROCESS EVALUATION IN A RANDOMIZED CONTROLLED TRIAL OF A COMPLEX INTERVENTION

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OBJECTIVES

- To discuss the purpose of integrating process evaluations in the overall evaluation of complex interventions
- To list process evaluation functions and measures
- To provide guidance for planning, designing, conducting, and writing up process evaluations
- To reflect on the process of conducting a process evaluation, integrated within a trial, to evaluate a public health nursing intervention – Nurse-Family Partnership

Nurse-Family Partnership

Helping First-Time Parents Succeed®

Nurse-Family Partnership CANADA

A COMPLEX NURSING INTERVENTION THAT TRANSFORMS LIVES

- Improved pregnancy outcomes
- Increased maternal economic self-sufficiency & reduced mortality
- Improved child health and development
  - …including prevention of child abuse and neglect

NFP INTERNATIONAL EVALUATION & IMPLEMENTATION

- Phase One: Adaptation of NFP program to local context – while ensuring fidelity to model
- Phase Two: Conduct pilot studies to determine feasibility and acceptability (Ontario)
- Phase Three: Conduct a randomized controlled trial; embedded process evaluation (BC)
- Phase Four: Continued refinement and expansion

PUBLIC HEALTH INTERVENTION

Adaptation and Implementation of the Nurse-Family Partnership in Canada

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ABSTRACT

Objectives: International agencies are required to adapt, pilot and then evaluate the effectiveness of the Nurse-Family Partnership (NFP) prior to broad implementation of this public health intervention. The objectives of this qualitative case study were to: 1) determine whether the NFP can be implemented in Canada with fidelity to the US model, and 2) identify the adaptations required to increase the acceptability of the intervention for service providers and families.

Participants: 108 low-income, first-time mothers in Hamilton, Ontario, received the NFP intervention. In-depth interviews were conducted with NFP clients (n=38), family members (n=14) and community professionals (n=24).

Setting: Hamilton, Ontario.

Intervention and Data Collection: An intensive nurse home visitation program delivered to women starting early in pregnancy and continuing until the child was two years old. Processes to adapt and implement the NFP were explored across seven focus groups with public health nurses and managers. Eighty documents were reviewed to identify implementation challenges. Data were analyzed using directed content analysis.

Outcomes: The NFP model elements are acceptable to Canadian health care providers, public health nurses and families receiving the intervention. The primary adaptation required was to reduce nurse caseloads from 25 to 20 active clients. Recommendations for adapting and implementing all model elements are described.

Conclusion: The NFP model requires minor adaptations to increase the acceptability of the intervention to Canadian stakeholders. A consistent approach to adapting the NFP program in Canada is necessary as provincial jurisdictions commit themselves to supporting an experimental evaluation of the effectiveness of the NFP.

Key words: Home visits; public health nurses; qualitative research; intervention research

La traduction du résumé se trouve à la fin de l'article.

Can J Public Health 2012;103(Suppl. 1):S42-S48.

The association of young maternal age and adverse maternal and infant health outcomes is a significant public health concern. Pregnancy at a younger age is associated with increased risk of poor maternal mental health,[1,2] poor educational outcomes[3,4] and economic difficulties.[5] Many risk factors associated with poverty and adolescent pregnancy, such as poor antenatal care, substance abuse, lower educational attainment and residence with a single parent, co-occur,[6] thereby creating a pervasive environment of extreme risk for children of young mothers.

Infants born into poverty are more likely to be premature or have low birth weights and are at an increased risk of mortality in the perinatal period through to adolescence.[7] They are also at increased risk of lower cognitive development and educational and social outcomes, increased risk of developmental delay[8,9] and poorer physical and mental health.[8,10] Young maternal age is also associated with increased risk of child maltreatment[11,12] and later effects such as substance abuse and risky behaviours. The infants also have a higher likelihood of growing up to become teenage parents themselves, thus perpetuating the cycle of risk.[10,13]

maternal and child health outcomes in targeted populations of young, low-income, first-time mothers and their families. Over three decades, the NFP has been tested in three large US-based randomized controlled trials (RCTs).[14,15] NFP goals include improvement in: 1) pregnancy outcomes, by promoting healthy prenatal behaviours; 2) child health and development, by promoting parents' competent care of their children; and 3) parents' life-course development. Nurses visit clients at home starting early in the preg-

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INTERVENTION

Catherine et al. BMC Health Services Research (2016) 16:349
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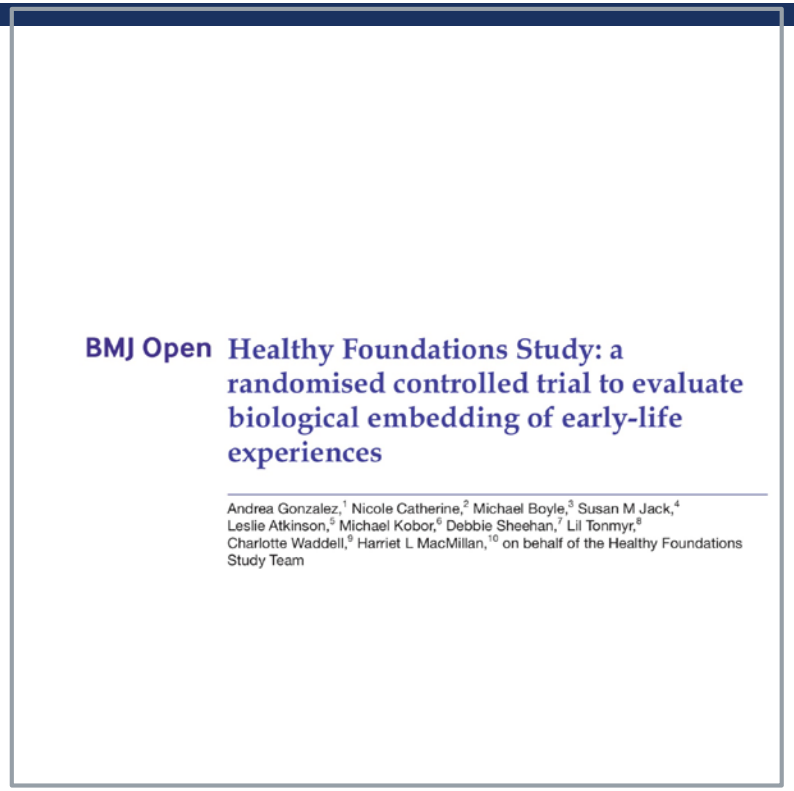
BMC Health Services Research

STUDY PROTOCOL Open Access

Improving children's health and development in British Columbia through nurse home visiting: a randomized controlled trial protocol

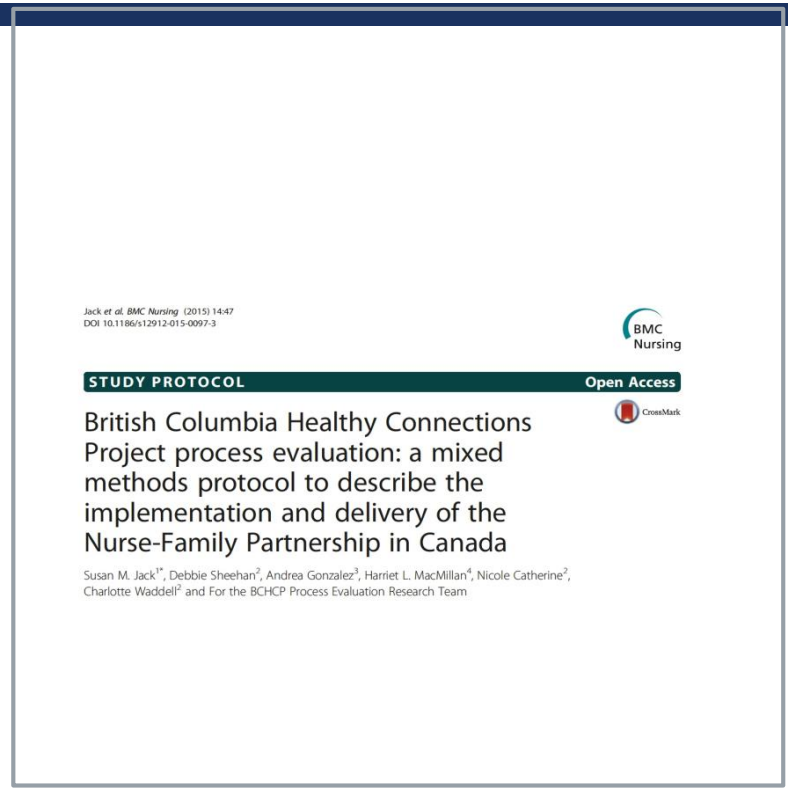
Nicole L. A. Catherine[1*], Andrea Gonzalez[2,3], Michael Boyle[2,3], Debbie Sheehan[1,2], Susan M. Jack[2,4], Kaitlyn A. Hougham[1], Lawrence McCandless[5], Harriet L. MacMillan[2,3], Charlotte Waddell[1] and For the British Columbia Healthy Connections Project Scientific Team



BMJ Open

Healthy Foundations Study: a randomised controlled trial to evaluate biological embedding of early-life experiences

Andrea Gonzalez,[1] Nicole Catherine,[2] Michael Boyle,[3] Susan M Jack,[4] Leslie Atkinson,[5] Michael Kobor,[6] Debbie Sheehan,[7] Lil Tonmyr,[8] Charlotte Waddell,[9] Harriet L MacMillan,[10] on behalf of the Healthy Foundations Study Team



Jack et al. BMC Nursing (2015) 14:47
DOI 10.1186/s12912-015-0097-3

BMC Nursing

STUDY PROTOCOL Open Access

British Columbia Healthy Connections Project process evaluation: a mixed methods protocol to describe the implementation and delivery of the Nurse-Family Partnership in Canada

Susan M. Jack[1*], Debbie Sheehan[2], Andrea Gonzalez[3], Harriet L. MacMillan[4], Nicole Catherine[2], Charlotte Waddell[2] and For the BCHCP Process Evaluation Research Team

EVALUATION OF NURSE-FAMILY PARTNERSHIP EFFECTIVENESS IN THE CANADIAN CONTEXT

WHY A PROCESS EVALUATION?

Need to understand which aspects of an intervention are important

Need to determine how different aspects of an intervention work together

Need to explore how an intervention can be implemented in a given/novel context

PROCESS EVALUATION OF A COMPLEX INTERVENTION: FUNCTIONS

- Describe intervention components
- Determine if intervention delivered with fidelity
- Describe implementation process
- Link intervention outcomes with implementation process
- Explain varied outcomes between agencies
- Improve theory-informed interventions

Linnan & Steckler (2002).
Saunders, Evans, and Joshi (2005)

PROCESS EVALUATION OF A COMPLEX INTERVENTION: MEASURES

- Fidelity (quality)
- Dose of intervention delivered
- Dose of intervention received
- Reach (participation rate)
- Recruitment (enrolment & retention)
- Implementation
- Context

Linnan & Steckler (2002).
Saunders, Evans, and Joshi (2005)

GUIDANCE FOR CARRYING OUT PROCESS EVALUATIONS

Planning

1. Define the parameters of relationships with intervention developers/implementers & research team
2. Ensure the research team has the correct expertise
3. Decide the degree of separation or integration between the process and outcome evaluation teams

Design and Conduct

4. Describe intervention/clarify causal assumptions
5. Identify key uncertainties; systematically select the most important questions to address
6. Select a combination of methods appropriate to the research questions

Moore et al (2015)

GUIDANCE FOR CARRYING OUT PROCESS EVALUATIONS

Analysis

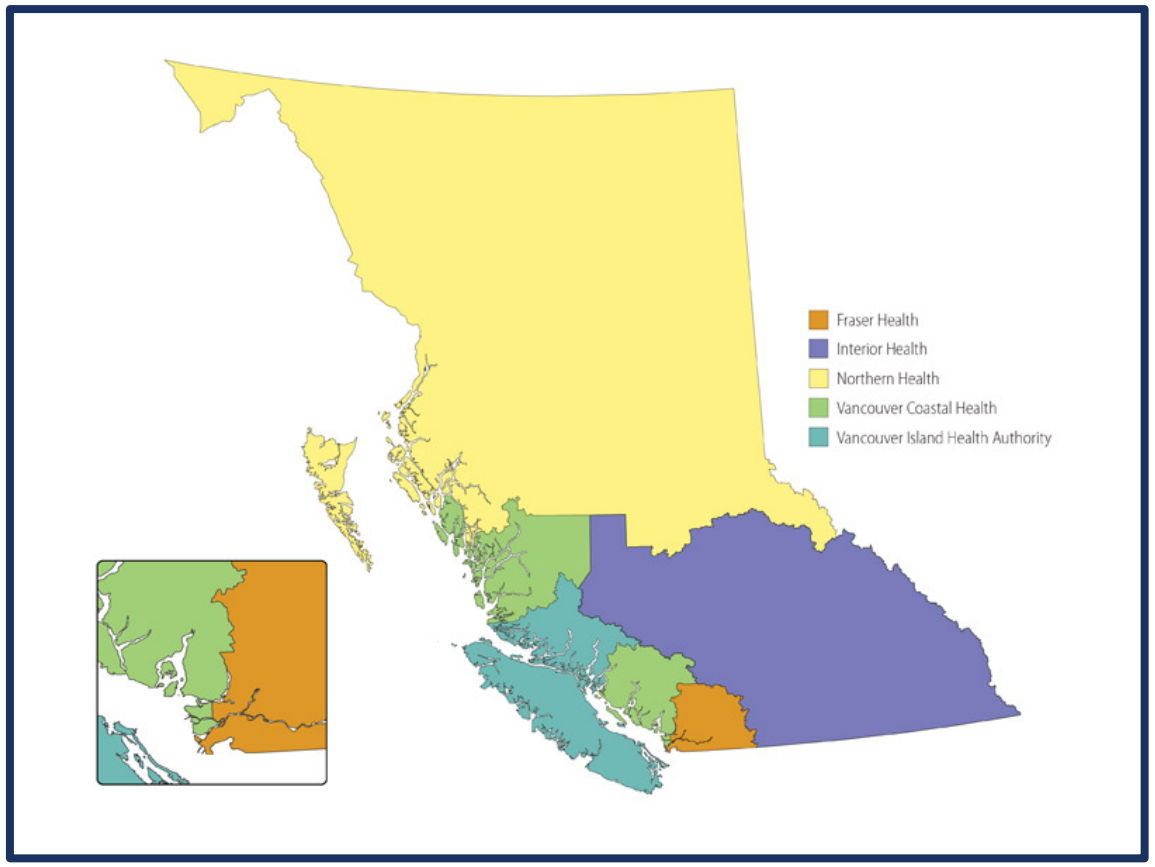
7. Provide descriptive quantitative information on fidelity, dose, reach
8. Integrate qualitative and quantitative data sets
9. Collect & analyze qualitative data iteratively so that themes emerge early and can be explored in later interviews
10. Ensure quantitative and qualitative data analyses build upon one another

Reporting

11. Identify existing reporting guidance specific to adopted methods
12. Disseminate findings to policy and practice stakeholders
13. If multiple articles published, ensure each article makes clear its context within the evaluation as a whole

Moore et al (2015)

BCHCP PROCESS EVALUATION OBJECTIVES



1. To determine the extent to which NFP is **delivered with fidelity** to the 18 model elements.
2. To **measure the dose of NFP** (delivered & received), **reach** (participation rate through pregnancy, infancy, toddlerhood), & **recruitment & retention**.
3. To explore the **acceptability** of NFP to PHNs, supervisors, NFP Provincial Coordinator & public health managers.
4. To describe PHNs' and supervisors' **experiences of the NFP education** program.
5. To **explore processes used to support NFP PHNs and supervisors** through reflective supervision, coaching and mentorship.
6. To **identify contextual factors that influence organizational adoption and implementation** of the NFP and utilization of the NFP visit-to-visit guidelines.
7. To **identify adaptations** to the NFP model elements to meet the needs of clients living in smaller suburban, rural or remote communities compared to the needs of clients living in urban communities.
8. To describe **PHNs' experiences** of delivering NFP to clients and families exposed to **mental health problems including substance misuse, intimate partner violence, or engagement with the child welfare system**.

MIXED METHODS STUDY DESIGN: CONCURRENT EMBEDDED VARIANT

BC Healthy Connections RCT (2013-2021)

Primary outcome: Average # of childhood injuries

Secondary:

Prenatal substance use (tobacco, alcohol)

Child development (cognitive ability, language development)

Child mental health (Behavior problems)

Maternal Life Course (subsequent pregnancies 24 months)

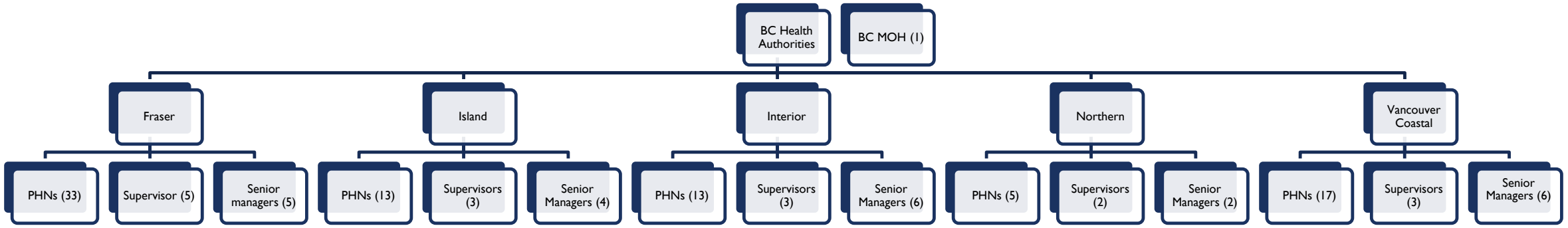
Process Evaluation (2013-2018)

Qualitative

Interpretive Description

Quantitative

Descriptive statistics



Health Authorities n=5
Public health nurses n= 81
Supervisor/Provincial Lead n= 17
Senior managers = 23

SITES AND SAMPLE

DATA COLLECTION

Qualitative Data			Quantitative Data	
Data Source	**Data Type**	**Frequency**	**Data Type**	**Frequency**
PHNs (Basic PE)	1:1 telephone interviews	Every 6 months	NFP Program Fidelity Data (BC MOH) -Stage of pregnancy (enrolment) -% of PHN time spent on each of 6 domains per home visit -total # home visits	Quarterly
PHNs (Expanded PE)	Focus groups (5 per/data collection period)	Every 6 months		
Supervisors	1:1 telephone interviews	Every 6 months		
Managers	1:1 telephone interviews	Every 12 months	Supervision Records	Completed monthly; aggregated every six months
Field Notes (maintained by research staff)	Observations & reflections	Ongoing		
Documents	Team meeting & case conference summary forms	Completed monthly; aggregated every 6 months		

POINTS FOR REFLECTION

Integrated knowledge translation

- Method creates opportunities to engage stakeholders early
- Facilitates recruitment, data collection and interpretation of results
- Stakeholder involvement ensures priority issues are included in data collection
- Opportunities to selectively share key findings
- However …want to ensure that PE findings do not impact RCT integrity/intervention delivery

BC Healthy Connections Project

BCHCP Process Evaluation Communique #1 | October 29, 2014

Model Element 1: Client participates voluntarily in the program
• PHNs emphasize to pregnant women that it is her personal choice to participate in the program, and she can decide to leave at anytime. • Clear communication within team and to external agencies that NFP is a voluntary and not mandated program • Element components reviewed in core education and within team meetings. Concept of a voluntary program is familiar to PHNS. • Many PHNs also engage in a process of seeking continuous consent once a woman is enrolled in the NFP. • Community agencies and professionals continue to recommend, or would like to recommend, that some socially and economically disadvantaged pregnant women be mandated to participate in the NFP. • Perception that some NFP clients may volunteer to participate in the program but their motivation is based on another professional (social worker or probation officer) persuading them that enrollment in the NFP is helpful to fulfill probation hours or to have a "better chance of keeping her baby." • Local health areas have taken the initiative to communicate information about the NFP Model elements to other agencies. Discussions about the voluntary nature of the NFP occur at multiple levels: 1) between the PHN and the client where the PHN explains the importance of making a personal decision to enroll in the program; 2) between the PHN and the supervisor in reflective supervision where discussions about client engagement and retention occur; 3) at the front-line level, most commonly between PHNs and Ministry of Child and Family Development social workers about the voluntary nature of the program; and 4) at an inter-organizational level, with NFP supervisors communicating directly to other agencies.

"I think that PHNs, public health nurses, are very comfortable with this concept of volunteer because they've been public health nurses for a long time and it's very common in public health to, to have informed consent and to understand that the clients are voluntary, that the

POINTS FOR REFLECTION: DATA TRIANGULATION & CONVERGENCE

Prevalence of violence in the lives of young pregnant women

- Any partner violence in the past year: 50%

- History of moderate/severe neglect, physical abuse, emotional abuse and/or sexual abuse at age 16 years or younger: 56%

Waddell et al (2018)

RICH CONTEXTUALIZATION OF DATA

- "She grew up in foster care herself…there was quite a history of sexual abuse and physical abuse…"
- "The father of my client was extremely abusive – physically, sexually, emotionally with my client, her siblings, and his wife…"
- "This woman's ex-husband comes and shoots this guy dead in front of the baby; and he's shooting at her…."
- "She was leaving her pimp and was scared that he was going to come and beat her up. She found some place to go…but her friend kicked her out, as this man called [the friend] and said, "I will kill you if you let her stay there.."
- "My client grew up in foster care because her mom was always on drugs, prostitution, violence, anger…."
- "Her parents were substance users… in and out of rehab..she was homeless at 13"

BCHCP Process Evaluation Data

POINTS FOR REFLECTION

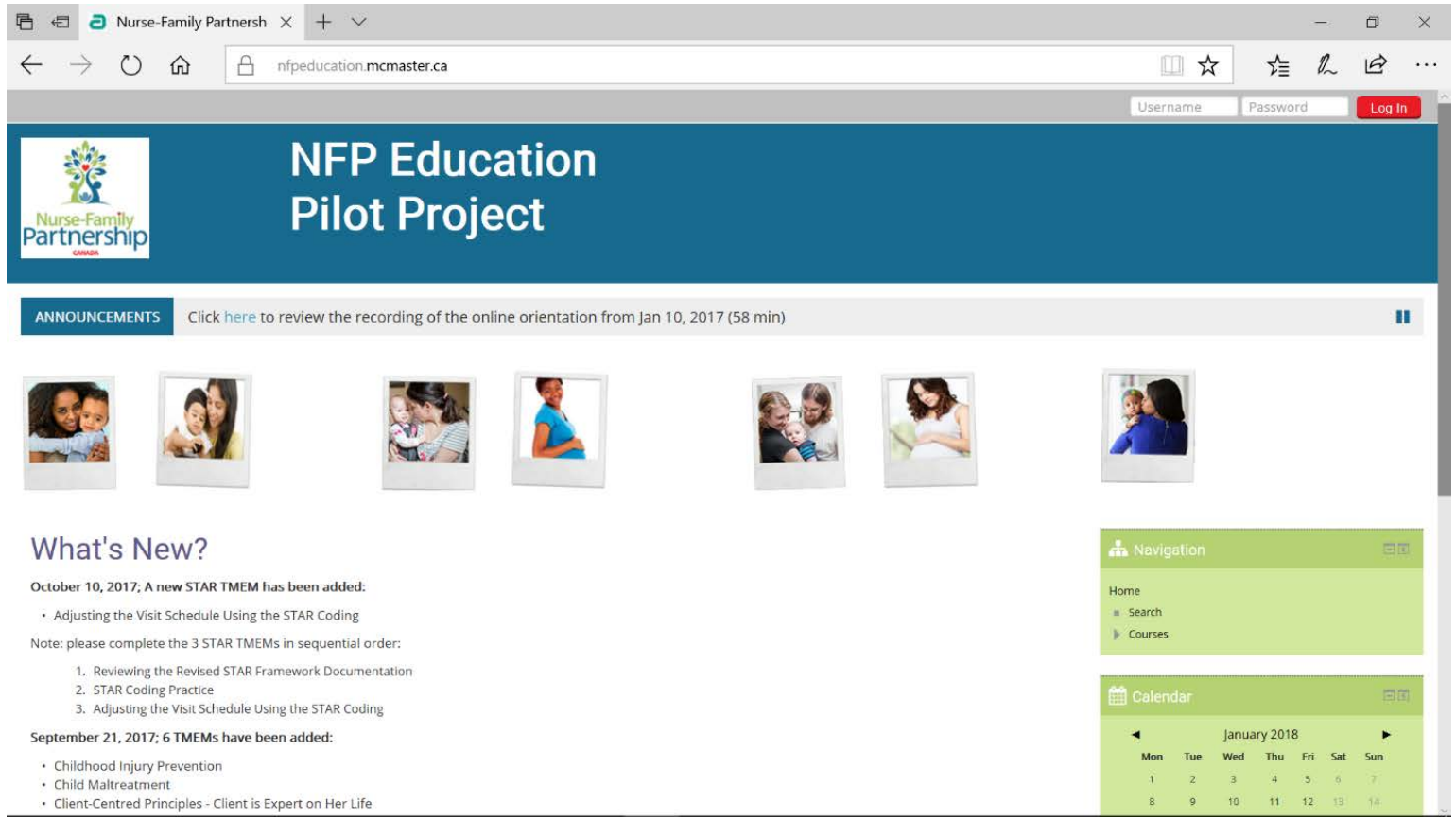
Close collaboration between RCT & PE research teams is ideal

- Ensure PE data around RCT outcomes are collected
- Able to explore and understand "implementation" issues in real-time
- Extensive time and planning required to secure data sharing agreements
- Planning (& perhaps some convincing) required to think about strategies to "write-up" results using "mixed" data

POINTS FOR REFLECTION

Utility of Findings

- Immediate application with respect to adapting/developing new materials for future use (*not to change intervention during trial)
- At end of trial – will be valuable to help explain unanticipated or novel findings



FINAL THOUGHTS

Mixed methods approaches to intervention evaluation allow for measurement of both process and outcomes

Process evaluation is an essential part of designing and testing complex interventions

Overall benefits of including process evaluations:

- Assess fidelity and quality of implementation
- Clarify causal mechanism
- Identify contextual factors associated with variation in outcomes

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